## 1

#### Interp: Debaters must disclose round reports on the 2020-21 NDCA LD wiki for every round they have debated this season. Round reports disclose which positions were read and gone for in every speech.

#### Violation: screenshot in the doc – they have one but it’s not a proper round report

A screenshot of a computer

Description automatically generated with medium confidence A screenshot of a computer

Description automatically generated with medium confidence

#### Standards:

#### 1] Level Playing Field – big schools can go around and scout and collect flows but independents are left in the dark so round reports are key to prep- they give you an idea of overall what layers debaters like going for so you can best prepare your strategy when you hit them. Accessibility first and independent voter – exclusion from debate is the worst violation of fairness and is a prereq to debating in the first place

#### 2] Strategy Education – round reports help novices understand the context in which positions are read by good debaters and help with brainstorming potential 1NCs vs affs – helps compensate for kids who can’t afford coaches to prep out affs.

#### Fairness – debate is a competitive game that requires fairness for objective evaluation. Outweighs because it’s the only intrinsic part of debate – all other rules can be debated over but rely on some conception of fairness to be justified.

#### Drop the debater – deter future abuse and set better norms for debate.

#### Competing interps – [a] reasonability is arbitrary and encourages judge intervention since there’s no clear norm, and B] it creates a race to the top where we create the best possible norms for debate.

#### No RVIs – a] illogical, you don’t win for proving that you meet the burden of being fair, logic outweighs since it’s a prerequisite for evaluating any other argument, b] RVIs incentivize baiting theory and prepping it out which leads to maximally abusive practices c) destroys substantive education by collapsing the debate to theory d) norming – forces me to go for bad norms bc otherwise I would lose

## 2

#### Interpretation: “medicines” is a generic bare plural. The aff may not defend that member nations of the World Trade Organization ought to reduce intellectual property protections for a medicine or subset of medicines.

Nebel 19. [Jake Nebel is an assistant professor of philosophy at the University of Southern California and executive director of Victory Briefs. He writes a lot of this stuff lol – duh.] “Genericity on the Standardized Tests Resolution.” Vbriefly. August 12, 2019. <https://www.vbriefly.com/2019/08/12/genericity-on-the-standardized-tests-resolution/?fbclid=IwAR0hUkKdDzHWrNeqEVI7m59pwsnmqLl490n4uRLQTe7bWmWDO_avWCNzi14> TG

Both distinctions are important. Generic resolutions can’t be affirmed by specifying particular instances. But, since generics tolerate exceptions, plan-inclusive counterplans (PICs) do not negate generic resolutions. Bare plurals are typically used to express generic generalizations. But there are two important things to keep in mind. First, generic generalizations are also often expressed via other means (e.g., definite singulars, indefinite singulars, and bare singulars). Second, and more importantly for present purposes, bare plurals can also be used to express existential generalizations. For example, “Birds are singing outside my window” is true just in case there are some birds singing outside my window; it doesn’t require birds in general to be singing outside my window. So, what about “colleges and universities,” “standardized tests,” and “undergraduate admissions decisions”? Are they generic or existential bare plurals? On other topics I have taken great pains to point out that their bare plurals are generic—because, well, they are. On this topic, though, I think the answer is a bit more nuanced. Let’s see why. “Colleges and universities” is a generic bare plural. I don’t think this claim should require any argument, when you think about it, but here are a few reasons. First, ask yourself, honestly, whether the following speech sounds good to you: “Eight colleges and universities—namely, those in the Ivy League—ought not consider standardized tests in undergraduate admissions decisions. Maybe other colleges and universities ought to consider them, but not the Ivies. Therefore, in the United States, colleges and universities ought not consider standardized tests in undergraduate admissions decisions.” That is obviously not a valid argument: the conclusion does not follow. Anyone who sincerely believes that it is valid argument is, to be charitable, deeply confused. But the inference above would be good if “colleges and universities” in the resolution were existential. By way of contrast: “Eight birds are singing outside my window. Maybe lots of birds aren’t singing outside my window, but eight birds are. Therefore, birds are singing outside my window.” Since the bare plural “birds” in the conclusion gets an existential reading, the conclusion follows from the premise that eight birds are singing outside my window: “eight” entails “some.” If the resolution were existential with respect to “colleges and universities,” then the Ivy League argument above would be a valid inference. Since it’s not a valid inference, “colleges and universities” must be a generic bare plural. Second, “colleges and universities” fails the [upward-entailment test](https://plato.stanford.edu/entries/generics/#IsolGeneInte) for existential uses of bare plurals. Consider the sentence, “Lima beans are on my plate.” This sentence expresses an existential statement that is true just in case there are some lima beans on my plate. One test of this is that it entails the more general sentence, “Beans are on my plate.” Now consider the sentence, “Colleges and universities ought not consider the SAT.” (To isolate “colleges and universities,” I’ve eliminated the other bare plurals in the resolution; it cannot plausibly be generic in the isolated case but existential in the resolution.) This sentence does not entail the more general statement that educational institutions ought not consider the SAT. This shows that “colleges and universities” is generic, because it fails the upward-entailment test for existential bare plurals. Third, “colleges and universities” fails the adverb of quantification test for existential bare plurals. Consider the sentence, “Dogs are barking outside my window.” This sentence expresses an existential statement that is true just in case there are some dogs barking outside my window. One test of this appeals to the drastic change of meaning caused by inserting any adverb of quantification (e.g., always, sometimes, generally, often, seldom, never, ever). You cannot add any such adverb into the sentence without drastically changing its meaning. To apply this test to the resolution, let’s again isolate the bare plural subject: “Colleges and universities ought not consider the SAT.” Adding generally (“Colleges and universitiesz generally ought not consider the SAT”) or ever (“Colleges and universities ought not ever consider the SAT”) result in comparatively minor changes of meaning. (Note that this test doesn’t require there to be no change of meaning and doesn’t have to work for every adverb of quantification.) This strongly suggests what we already know: that “colleges and universities” is generic rather than existential in the resolution.

#### It applies to “medicines” – 1] upward entailment test – “member nations of the World Trade Organization ought to reduce intellectual property protections for medicines” doesn’t entail that member nations of the WTO ought to reduce IPP for drugs because it doesn’t prove that marijuana protections should be reduced 2] adverb test – adding “always” to the res doesn’t substantially change its meaning because reduce is permanent.

#### Violation: They spec Covid related medicines

#### Standards:

#### [1] precision – the counter-interp justifies them arbitrarily doing away with random words in the resolution which decks negative ground and preparation because the aff is no longer bounded by the resolution. Independent voter for jurisdiction – the judge doesn’t have the jurisdiction to vote aff if there wasn’t a legitimate aff.

#### [2] Limits and ground – their model allows affs to defend anything from Covid vaccines to HIV drugs to Insulin— there's no universal DA since each has different functions and political implications — that explodes neg prep and leads to random medicine of the week affs which makes cutting stable neg links impossible — limits key to reciprocal engagement since they create a caselist for neg prep and it takes out ground like DAs to certain medicines which are some of the few neg generics when affs spec medicines.

#### [3] TVA solves – you could’ve read your plan as an advantage under a whole res advocacy.

## 3

#### Morality must be grounded in a priori truth to guide action, otherwise everyone would have different ethical codes and follow different rules. And, truth exists independent of human experience since certain things can be self-proving, i.e. a triangle has three sides. This is the difference between a priori and a posteriori. Things that are true by observation are just true by a matter of chance. For example, the cat may be on the mat, but we can also conceive of a world in which the cat is not on the mat. In contrast, we can’t conceive of a world in which a triangle does not have three sides since it is tautologically true. Reject a posteriori truth since they are just arbitrary states of being, not constitutive of ethics.

#### And, a priori truth has to apply to everyone: [a] absent universal ethics, morality becomes arbitrary and fails to guide action, which means that ethics is rendered useless. [b] it’s a tautological contradiction: any non-universal norm justifies someone’s ability to impede on your ends, which also means universalizability acts as a side constraint on all other frameworks.

#### Thus, the standard is consistency with willing universal maxims.

### 1NC – Offense

#### 1] Intellectual property is an inalienable personal right of economic use

**Pozzo 6** Pozzo, Riccardo. “Immanuel Kant on Intellectual Property.” Trans/Form/Ação, vol. 29, no. 2, 2006, pp. 11–18., doi:10.1590/s0101-31732006000200002. SJ//DA recut Cookie JX

Corpus mysticum, opus mysticum, propriété incorporelle, proprietà letteraria, geistiges Eigentum. All these terms mean **intellectual property, the existence of which is intuitively clear because of the unbreakable bond that ties the work to its creator.** The book belongs to whomever has written it, the picture to whomever has painted it, the sculpture to whomever has sculpted it; and this independently from the number of exemplars of the book or of the work of art in their passages from owner to owner. The initial bond cannot change and it ensures the author authority on the work. Kant writes in section 31/II of the Metaphysics of Morals: “Why does unauthorized publishing, which strikes one even at first glance as unjust, still have an appearance of being rightful? Because on the one hand a book is a corporeal artifact (opus mechanicum) that can be reproduced (by someone in legitimate possession of a copy of it), so that there is a right to a thing with regard to it. On the other hand a book is also a mere discourse of the publisher to the public, which the publisher may not repeat publicly without having a mandate from the author to do so (praestatio operae), and this is a right against a person. The error consists in mistaking one of these rights for the other” (Kant, 1902, t.6, p.290). The corpus mysticum, **the work considered as an immaterial good, remains property of the author on behalf of the original right of its creation. The corpus mechanicum consists of the exemplars of the book or of the work of art. It becomes the property of whoever has bought the material object in which the work has been reproduced or expressed.** Seneca points out in De beneficiis (VII, 6) the difference between owning a thing and owning its use. He tells us that the bookseller Dorus had the habit of calling Cicero’s books his own, while there are people who claim books their own because they have written them and other people that do the same because they have bought them. Seneca concludes that the books can be correctly said to belong to both, for it is true they belong to both, but in a different way **The peculiarity of intellectual property consists thus first in being indeed a property, but property of an action; and second in being indeed inalienable, but also transferable in commission and license to a publisher. The bond the author has on his work confers him a moral right that is indeed a personal right. It is also a right to exploit economically his work in all possible ways, a right of economic use, which is a patrimonial right. Kant and Fichte argued that moral right and the right of economic use are strictly connected, and that the offense to one implies inevitably offense to the other.** In eighteenth-century Germany, the free use came into discussion among the presuppositions of a democratic renewal of state and society. In his Supplement to the Consideration of Publishing and Its Rights, Reimarus asked writers “instead of writing for the aristocracy, to write for the tiers état of the reader’s world.” (Reimarus, 1791b, p.595). **He saluted with enthusiasm the claim of disenfranchising from the monopoly of English publishers expressed in the American Act for the Encouragement of Learning of May 31, 1790. Kant, however, was firm in embracing intellectual property. Referring himself to Roman Law, he asked for its legislative formulation not only as patrimonial right, but also as a personal right.** In Of the Illegitimity of Pirate Publishing, he considered the moral faculties related to **intellectual property as an “inalienable right (ius personalissimum) always himself to speak through anyone else, the right, that is, that no one may deliver the same speech to the public other than in his (the author’s) name”** (Kant, 1902, t.8, p.85). Fichte went farther in the Demonstration of the Illegitimity of Pirate Publishing. **He saw intellectual property as a part of his metaphysical construction of intellectual activity, which was based on the principle that thoughts “are not transmitted hand to hand, they are not paid with shining cash, neither are they transmitted to us if we take home the book that contains them and put it into our library.** In order to make those thoughts our own an action is still missing: we must read the book, meditate – provided it is not completely trivial – on its content, consider it under different aspects and eventually accept it within our connections of ideas” (Fichte, 1964, t.I/1, p.411). At the center of the discussion was the practice of reprinting books in a pirate edition after having them reset word after words after an exemplar of the original edition. Given Germany’s division in a myriad of small states, the imperial privilege was ineffective against pirate publishing. Kant and Fichte spoke for the acceptance of the right to defend the work of an author by the usurpations of others so that he may receive a patrimonial advantage from those who utilize the work acquiring new knowledge and/or an aesthetic experience. In particular, Fichte declared the absolute primacy of the moral faculties within the corpus mysticum. He divided the latter into a formal and a material part. “This intellectual element must be divided anew into what is material, the content of the book, the thoughts it presents; and the form of these thoughts, the manner in which, the connection in which, the formulations and the words by means of which the book presents them” (Fichte, 1964, t.I/1, p.411). Fichte’s underlining the author’s exclusive right to the intellectual content of his book – “the appropriation of which through another is physically impossible” (ibid.) – brought him to the extreme of prohibiting any form of copy that is not meant for personal use. In Publishing Considered anew, Reimarus considered on the contrary copyright in its patrimonial aspects as a limitation to free trade: “What would not happen were a universal protection against pirate publishing guaranteed? Monopoly and safer sales certainly do not procure convenient price; on the contrary, they are at the origin of great abuses. The only condition for convenient price is free-trade, and one cannot help noticing that upon the appearance of a private edition, publishers are forced to substantially lower the price of a book” (Reimarus, 1791a, pp.402-3). Reimarus admitted of being unable to argue in terms of justice. Justice was of no bearing, he said, for whom, like himself, considered undemonstrated the author’s permanent property of his work (herein supported by the legislative vacuum of those years). What mattered, he said, was equity. In sum, Reimarus anticipated today’s stance on free use by referring to the principle that public interest on knowledge ought to prevail on the author’s interest and to balance the copyright. Moreover, Reimarus extended his argument beyond the realm of literary production to embrace, among others, the today vital issue of pharmaceutical production on patented receipts. “Let us suppose that at some place a detailed description for the preparation of a good medicine or of any other useful thing be published, why may not somebody who lives in places that are far away from that one copy it to use it for his own profit and but must instead ask the original publisher for the issue of each exemplar?” (Reimarus, 1791b, t.2, pp.584). To sum up, Reimarus’s stance does not seem respondent to rule of law. For in all dubious case the general rule ought to prevail, fighting intellectual property with anti-monopolistic arguments in favor of free trade brings with itself consequences that are not tranquilizing also for the ones that are expected to apply the law. By resetting literary texts, one could obviously expurgate some errors. More frequently, however, some were added, given the exclusively commercial objectives of the reprints. The valid principle was, thus, that reprints were less precise than original editions, but they were much cheaper for the simple reason that the pirate publisher had a merely moral obligation against the author and the original publisher. In fact, he was not held to pay any honorarium to the author upon handling over the manuscript, nor to paying him royalties, nor to pay anything to the original publisher. The only expense in charge of the pirate publisher was buying the exemplar of the original edition out of which he was to make, as we say today, a free use.

#### 2]The aff violates the categorical imperative and is non-universalizable- governments have a binding obligation to protect creations

**Van 18** (We didn’t say the author’s last name because the phonetic pronunciation is the same as a slur.) Raymond Van Dyke, 7-17-2018, "The Categorical Imperative for Innovation and Patenting," IPWatchdog, <https://www.ipwatchdog.com/2018/07/17/categorical-imperative-innovation-patenting/id=99178/> SJ//DA recut SJKS

As we shall see, applying **Kantian logic entails first acknowledging some basic principles; that the people have a right to express themselves, that that expression (the fruits of their labor) has value and is theirs (unless consent is given otherwise), and that government is obligated to protect people and their property. Thus, an inventor or creator has a right in their own creation, which cannot be taken from them without their consent.** So, employing this canon, **a proposed Categorical Imperative (CI) is the following Statement: creators should be protected against the unlawful taking of their creation by others. Applying this Statement to everyone, i.e., does the Statement hold water if everyone does this, leads to a yes determination. Whether a child, a book or a prototype, creations of all sorts should be protected, and this CI stands.** This result also dovetails with the purpose of government: to protect the people and their possessions by providing laws to that effect, whether for the protection of tangible or intangible things. **However, a contrary proposal can be postulated: everyone should be able to use the creations of another without charge. Can this Statement rise to the level of a CI? This proposal, upon analysis would also lead to chaos. Hollywood, for example, unable to protect their films, television shows or any content, would either be out of business or have robust encryption and other trade secret protections, which would seriously undermine content distribution and consumer enjoyment.** Likewise, inventors, unable to license or sell their innovations or make any money to cover R&D, would not bother to invent or also resort to strong trade secret. Why even create? This approach thus undermines and greatly hinders the distribution of ideas in a free society, which is contrary to the paradigm of the U.S. patent and copyright systems, which promotes dissemination. By allowing freeriding, innovation and creativity would be thwarted (or at least not encouraged) and trade secret protection would become the mainstay for society with the heightened distrust.

#### 3]The aff encourages free riding- that treats people as ­means to an end and takes advantage of their efforts which violates the principle of humanity

**Van 2** (We didn’t say the author’s last name because the phonetic pronunciation is the same as a slur.) Raymond Van Dyke, 7-17-2018, "The Categorical Imperative for Innovation and Patenting," IPWatchdog, <https://www.ipwatchdog.com/2018/07/17/categorical-imperative-innovation-patenting/id=99178/> SJ//DA recut SJKS

Also, **allowing the free taking of ideas, content and valuable data, i.e., the fruits of individual intellectual endeavor**, would disrupt capitalism in a radical way. **The resulting more secretive approach in support of the above free-riding Statement** would be akin to a Communist environment **where the State owned everything and the citizen owned nothing, i.e., the people “consented” to this. It is, accordingly, manifestly clear that no reasonable and supportable Categorical Imperative can be made for the unwarranted theft of property, whether tangible or intangible,** apart from legitimate exigencies.

#### IPs are a necessary check on companies free-riding off associations of quality.

Wong et al 20 [Liana, Ian, and Shayerah; Analyst in International Trade and Finance; Specialist in International Trade and Finance; Specialist in International Trade and Finance; “Intellectual Property Rights and International Trade,” \*Updated\* 5/12/20; CRS; <https://www.everycrsreport.com/files/20200512_RL34292_2023354cc06b0a4425a2c5e02c0b13024426d206.pdf>] Justin

Trademark protection in the United States is governed jointly by state and federal law. The main federal statute is the Lanham Act of 1946 (Title 15 of the United States Code). Trademarks permit the seller to use a distinctive word, name, symbol, or device to identify and market a product or company. Marks can also be used to denote services from a particularly company. The trademark allows quick identification of the source of a product, and for good or ill, can become an indicator of a product's quality. If for good, the trademark can be valuable by conveying an instant assurance of quality to consumers. Trademark law serves to prevent other companies with similar merchandise from free-riding on the association of quality with the trademarked item. Thus, a trademarked good may command a premium in the marketplace because of its reputation. To be eligible for a trademark, the words or symbol used by the business must be sufficiently distinctive; generic names of commodities, for example, cannot be trademarked. Trademark rights are acquired through use or through registration with the PTO.

A related concept to trademarks is geographical indications (GIs), which are also protected by the Lanham Act. The GI acts to protect the quality and reputation of a distinctive product originating in a certain region; however, the benefit does not accrue to a sole producer, but rather the producers of a product originating from a particular region. GIs are generally sought for agricultural products, or wines and spirits. Protection for GIs is acquired in the United States by registration with the PTO, through a process similar to trademark registration.

## Case

### FW

#### [1] Overview: your framework is consequentialist - Ungrievability is an aggregative concept- people are not rendered ungrievable simply because one person considers them so- it’s because a certain larger # of people treat them that way. That means it’s a scalar, not binary concept.

**But consequences fail –**

**[1] Induction fails. Induction assumes that things will always happen the same way in the future as they have in the past. But this begs the question of how we know what happened in the past will happen in the future. Thus, induction is logically fallacious.**

**[2] Prediction is impossible. Any action can lead to a domino effect that can have disastrous impacts in the end. If I sneeze, it could lead to a butterfly effect that eventually causes my sneeze to form into a hurricane and kill thousands.**

#### [3] Aggregate pleasure is non-sensical - five headaches don’t equal a migraine – pain is bad for each person not collectively

### Advantage

#### Hold them to a high bar to explain solvency and distribution of vaccines, global vaccine distribution doesn’t happen with a snap of your fingers – if you don’t have a clear picture about how the aff produces enough vaccines and how they distribute those vaccines, don’t vote for them

#### Skill Disparities and Trade Secrets – Moderna proves IP isn’t the root cause.

Silverman 3-15 Rachel Silverman 3-15-2021 "Waiving vaccine patents won’t help inoculate poorer nations" <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/> (Rachel Silverman is a policy fellow at the Center for Global Development)//Duong

Reality is more complicated, however. Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have **little effect**. It could even backfire, with companies using the move as an excuse to disengage from global access efforts. There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents. The Moderna vaccine illustrates the limits of freeing up intellectual property. Moderna announced in October that it would **not enforce IP rights** on its coronavirus vaccine — and yet it has **taken no steps to share information** about the vaccine’s design or manufacture, citing commercial interests in the underlying technology. Five months later, production of the Moderna vaccine remains entirely under the **company’s direct control** within its owned and contracted facilities. Notably, Moderna is also the only manufacturer of a U.S.- or British-approved vaccine not yet participating in Covax, a global-aid-funded effort (including a pledged $4 billion from the United States) to purchase vaccines for use in low- and middle-income countries. It is true, however, that activist pressure — including threats to infringe upon IP rights — can encourage originators to enter into voluntary licensing arrangements. So the global movement to liberate the vaccine patents may be useful, even if some advocates make exaggerated claims about the effects of waivers on their own. We focused on covid. Now our other patients are suffering. One reason patent waivers are unlikely to help much in this case is that vaccines are harder to make than ordinary drugs. Because most drugs are simple chemical compounds, and because the composition of the compounds is easily analyzable, competent chemists can usually reverse-engineer a production process with relative ease. When a drug patent expires, therefore — or is waived — generic companies can readily enter the market and produce competitive products, lowering prices dramatically. Vaccines, in contrast, are complex biological products. Observing their contents is insufficient to allow for imitation. Instead, to produce the vaccine, manufacturers need access to the developer’s “soft” IP — the proprietary recipe, cell lines, manufacturing processes and so forth. While some of this information is confidentially submitted to regulators and might theoretically be released in an extraordinary situation (though not without legal challenge), manufacturers are at an enormous disadvantage without the originator’s cooperation to help them set up their process and kick-start production. Even with the nonconsensual release of the soft IP held by the regulator, the process of trial and error would cause long delays in a best-case scenario. Most likely, the effort would end in expensive failure. Manufacturers also need certain raw ingredients and other materials, like glass vials and filtration equipment; overwhelming demand, paired with disruptive export restrictions, has constricted the global availability of some of these items.

#### At solvency ev

#### [1] Nothing about your solvency evidence or your advocacy text pushes companies to share their trade secrets.

#### [2] You say legal certainty and harassment to Big Pharma would push companies to share info, but Moderna hasn’t enforced IP for months and nothing has changed- companies don’t have the incentive to willingly share secrets that would cost them their control of the monopoly bc they lose profits

### 1NC – Infrastructure Deficit

#### MRNA expert shortages.

Garde et al 21 [Damian Garde (National Biotech Reporter), Helen Branswell (Senior Writer, Infectious Disease)Matthew Herper (Senior Writer, Medicine, Editorial Director of Events), 5/6/21, Waiver of patent rights on Covid-19 vaccines, in near term, may be more symbolic than substantive, <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/>] Justin

In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses.

That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines.

“There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting.

While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing.

“In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said.

#### Existing companies solve scale-up, but other companies don’t have the capabilities.

Lowe 21 [Derek; BA from Hendrix College and PhD in organic chemistry from Duke before spending time in Germany on a Humboldt Fellowship on his post-doc. He’s worked for several major pharmaceutical companies since 1989 on drug discovery projects against schizophrenia, Alzheimer’s, diabetes, osteoporosis and other diseases; 2/2/21; Myths of Vaccine Manufacturing; <https://www.science.org/content/blog-post/myths-vaccine-manufacturing>] Justin

Ah, but now we get back to Step Four. As Neubert says, "Welcome to the bottleneck!" Turning a mixture of mRNA and a set of lipids into a well-defined mix of solid nanoparticles with consistent mRNA encapsulation, well, that's the hard part. Moderna appears to be doing this step in-house, although details are scarce, and Pfizer/BioNTech seems to be doing this in Kalamazoo, MI and probably in Europe as well. Everyone is almost certainly having to use some sort of specially-built microfluidics device to get this to happen - I would be extremely surprised to find that it would be feasible without such technology. Microfluidics (a hot area of research for some years now) involves liquid flow through very small channels, allowing for precise mixing and timing on a very small scale. Liquids behave quite differently on that scale than they do when you pour them out of drums or pump them into reactors (which is what we're used to in more traditional drug manufacturing). That's the whole idea. My own guess as to what such a Vaccine Machine involves is a large number of very small reaction chambers, running in parallel, that have equally small and very precisely controlled flows of the mRNA and the various lipid components heading into them. You will have to control the flow rates, the concentrations, the temperature, and who knows what else, and you can be sure that the channel sizes and the size and shape of the mixing chambers are critical as well.

These will be special-purpose bespoke machines, and if you ask other drug companies if they have one sitting around, the answer will be "Of course not". This is not anything close to a traditional drug manufacturing process. And this is the single biggest reason why you cannot simply call up those "dozens" of other companies and ask them to shift their existing production

### 1NC - Raw Material Shortages

#### List of supply shortages – there is no way the aff solves, but they decrease available vaccines.

[Laurie Garrett 21, (Columnist at Foreign Policy and former senior fellow for global health at the Council on Foreign Relations). 5/7/21, Stopping Drug Patents Has Stopped Pandemics Before, Foreign Policy, <https://foreignpolicy.com/2021/05/07/stopping-drug-patents-pandemics-coronavirus-hiv-aids/>] Justin

The vaccines aren’t easy to make. Manufacturing errors in a Maryland Emergent BioSolutions factory caused an 86 percent plummet in Johnson & Johnson vaccine supplies in early April. Complex steps in the process of isolating, purifying, preserving, storing, and delivering COVID-19 immunizations are each error-prone and require long lists of specialized chemicals and machinery.

The world is in the grips now of pipette tips shortages—used to suck out chemicals and viral samples from test tubes in key steps of vaccine making. Syringes are in short supply, prompting vaccinators to toss vaccine supplies for lack of means to administer them. The sterile containers used to hold vaccines are running out. From the earliest days of the 2020 pandemic, the sorts of protective gear and machinery vaccine researchers and makers require have been in short supply, exacerbated by trade tensions between the United States and China. Swabs used for COVID-19 testing and all aspects of equipment cleaning in sterile conditions are held up in a grotesque family dispute in Maine. There aren’t enough centrifuge tubes made worldwide to spin down cell samples. Moderna and Pfizer are constantly scrambling to find the ingredients used to make the microscopic fatty balls, called liposomes, that house the mRNA molecules and carry them safely into the bloodstream. Even the nucleic acids used to construct mRNA and a long list of special enzymes used to purify those samples are in horribly short supply, largely because their use overlaps with the manufacture of COVID-19 tests. Because such delicate chemicals and proteins must be handled at deep-freeze temperatures and transported swiftly for immediate use, the entire supply chain is vulnerable to the simplest of catastrophes: weather at an airport, a car crash that blocks truck traffic, power outages, or competition for cargo space.

Although waiving TRIPS requirements on COVID-19 vaccines is a spectacular, historic gesture, would-be generic makers worldwide will soon discover their efforts are stymied not by patents but for want of Avanti Polar Lipids’ liposome ingredients, Flexsafe RM special bags to hold liquid vaccines in bulk, phosphate-buffered saline solution, Distearoylphosphatidylcholine for liposome-making, 5’ cap for mRNA made by TriLink BioTechnologies, RNA polymerases—the list goes on, and on, and on. As the number of would-be vaccine makers grows, so will demand for thousands of such items, putting pressure on companies that are, in many cases, mom-and-pop operations. Worse, pressure on supplies critical for COVID-19 vaccine making is already resulting in a production loss of vital medicines for other diseases.

#### Raw materials take years to scaleup.

Newey et al 21 [Sarah Newey*;* Anne Gulland*;* Jennifer Rigby, (GLOBAL HEALTH SECURITY CORRESPONDENTS at the telegraph) *and* Samaan Lateef (Reporting IN INDIA) 6/1/21, Vaccinating the world: the obstacles hindering global rollout – and how to overcome them, Telegraph, <https://www.telegraph.co.uk/global-health/science-and-disease/vaccinating-the-world/>] Justin

But perhaps the strongest argument against waivers is this: in October Moderna, one of the producers of new mRNA vaccines, actually offered an IP waiver. No-one has yet taken it up. Instead, “the biggest obstacle is raw materials,” says Dr Richard Torbett, chief executive of the Association of the British Pharmaceutical Industry. “All of the companies are saying we could produce more if we only had more glass vials, or filters, or bio bags.” Again, this is a daunting challenge – the Pfizer vaccine, for example, has 260 ingredients that come from 60 companies in 19 different countries. Many of these products are highly specialised and it will take many months, perhaps years, to ramp production of them up. “We’re very likely to see continued shortages that set back some of the vaccine producers for several months,” says Rasmus Bech Hansen, chief executive of Airfinity, adding that it is becoming harder for manufacturers with new jabs to secure the needed supplies – CureVac is already facing this problem, for example. The third challenge is perhaps harder to tackle. Vaccines are biological products and the manufacturing process does not always go smoothly. According to Airfinity, 1.73bn doses have been distributed worldwide, far short of the 4.5bn initially projected by big pharma. An overambitious manufacturing target is largely to blame for the gap. [AstraZeneca’s row with Europe](https://www.telegraph.co.uk/news/2021/05/09/eu-says-wont-renew-astrazeneca-contract-pivots-towards-pfizers/), for instance, was triggered by a lower yield at factories than hoped. Meanwhile Russia has produced only around 42m doses – compared to 400m from AstraZeneca and Pfizer – amid difficulties producing the second dose of Sputnik V, which uses different adenoviruses in the first and second shot.

#### The aff causes a scramble for limited resources by manufacturers with no experience – turns case.

Breuninger 21 [Kevin; Specialist at CNBC; “Pfizer CEO opposes U.S. call to waive Covid vaccine patents, cites manufacturing and safety issues,” CNBC; 5/7/21; <https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html>] Justin

“Currently, infrastructure is not the bottleneck for us manufacturing faster,” Bourla wrote in a dear colleague letter posted on LinkedIn. “The restriction is the scarcity of highly specialized raw materials needed to produce our vaccine.”

Pfizer’s vaccine requires 280 different materials and components that are sourced from 19 countries around the world, Bourla said. He contended that without patent protections, entities with much less experienced than Pfizer at manufacturing vaccines will start competing for the same ingredients.

“Right now, virtually every single gram of raw material produced is shipped immediately into our manufacturing facilities and is converted immediately and reliably to vaccines that are shipped immediately around the world,” Bourla wrote.

He predicted that the proposed waiver “threatens to disrupt the flow of raw materials.”

“It will unleash a scramble for the critical inputs we require in order to make a safe and effective vaccine,” Bourla wrote.

“Entities with little or no experience in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk,” the CEO wrote.